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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,711

04/14/2004

Leonard W. Kaplan

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,711	Applicant(s) KAPLAN ET AL.	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 75-78 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "generally" in claim **75** is a relative term which renders the claim indefinite. The term "generally" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, one of ordinary skill in the art has not been provided adequate disclosure on the degree of "generally parallel".

The term "substantially" in claim **75** is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here, one of ordinary skill in the art has not been provided adequate disclosure on the degree of "substantially across" and "substantially vertical".

Claims **76-78** are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75-76 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunce et al (5,881,721).

Bunce et al teach an apparatus for orienting and positioning an elongate object, for example, capsules of medicament, comprising a passage for receiving an individual capsule in a preferred orientation, a container for holding a bulk supply of capsules, and a ramp surface which directs a capsule towards the passage when the device is positioned such that the passage extends vertically downwardly from the container (see abstract and summary). The apparatus comprises a tube for receiving the object to be oriented and dispensed, a ramp surface extending substantially across the tube from one wall to an opposite wall thereof; and an elongate dispensing passage having a diameter less than that of the tube and being sized to receive the object to be dispensed only when the axis of the object is generally parallel to the axis of the passage, the passage being adjacent to one wall of the tube such that the axis of the passage is parallel to but radially offset from an axis of the tube, whereby when the apparatus is positioned with the passage below the tube and the axis of the passage substantially

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vertical, an elongate object located in the tube will be guided by the ramp surface towards the inlet end of the passage (see text and claims 1, 10 and 11).

Bunce also discloses that the said capsule dispensed by the said apparatus contains a medicinal or therapeutic agent. The suitable active agents include bronchodilators, corticosteroids and anti-inflammatory agents. Bronchodilators include pirbuterol, fenoterol, reproterol, salbutamol (albuterol), salmeterol, etc. Corticosteroids include beclomethasone, fluticasone, etc. The said medicaments are useful for treating disorders such as respiratory disorders (see col. 5, lines 22-38 and claim 15)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunce et al (5,881,721) in view of Sequeira et al (6,057,307).

Bunce et al, discussed above, discloses that suitable medicaments for the said apparatus and delivery to the lungs include bronchodilators and corticosteroids, but lacks specific disclosure on mometasone as required by instant claim 77.

Sequeira et al teach use of mometasone furoate for treating airway passage and lung diseases aerosolized in the form of dry powder, as well as solution or suspensions (see abstract). Sequeira et al teach that mometasone furoate is administered, for example, by oral inhalation to treat diseases of the lower and/or upper airway passage and/or lungs, may be used as monotherapy or as adjunct therapy with for example a bronchodilator such as albuterol (salbutamol) or theophylline (see col. 5, lines 8-40). An example of a respiratory disorder is asthma (see col. 8, lines 14-16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, given the device and formulations of Bunce et al for treating respiratory disorders to have looked in the art for other corticosteroids useful for such treatments, as taught by Sequeira et al, with a reasonable expectation of successfully preparing a formulation that is suitable for combination therapies and works well in the powder form. In other words, the combination of Bunce et al and Sequeira et al references provides adequate disclosure to one of ordinary skill in the art to make and use the invention as claimed. Furthermore, the claim would have been obvious because the simple substitution of one known, equivalent element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Mina Haghighatian', with a large, stylized loop at the end.

Mina Haghighatian
Patent Examiner
August 27, 2007